

## PATENT COOPERATION TREATY

REC'D 18 JUL 2005

From the  
INTERNATIONAL SEARCHING AUTHORITY

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To:  
CRAIG J. ARNOLD  
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NEW YORK, NY 10016WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing  
(day/month/year)

14 JUL 2005

Applicant's or agent's file reference

FOR FURTHER ACTION

See paragraph 2 below

50425/202

International application No.

International filing date (day/month/year)

Priority date (day/month/year)

PCT/US04/33176

08 October 2004 (08.10.2004)

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International Patent Classification (IPC) or both national classification and IPC

IPC(7): C07H 21/04; C12N 15/00; C07K 16/00, 14/00; A61K 39/395, 38/00 and US Cl.: 536/23.53; 435/320.1, 7, 6, 325, 326; 530/300, 387.3, 387.2; 424/130.1; 514/2

Applicant

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## 1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

## 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

## 3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US

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Form PCT/ISA/237 (cover sheet) (January 2004)

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US04/33176

**Box No. I Basis of this opinion**

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_ which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing  
☐ table(s) related to the sequence listing

b. format of material

- ☐ in written format  
☐ in computer readable form

c. time of filing/furnishing

- ☐ contained in international application as filed.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/US04/33176

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>1-116</u>	YES
	Claims <u>NONE</u>	NO
Inventive step (IS)	Claims <u>24-77, 93-102, 104-109, 111-115</u>	YES
	Claims <u>1-23, 78-92, 103, 110, 116</u>	NO
Industrial applicability (IA)	Claims <u>1-116</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-23, 78-92, 103, 110, 116 lacks an inventive step under PCT Article 33(3) as being obvious over Fais et al in view of Damle et al and Valetto et al.

The claims are summarized as light and heavy chain genes which are members of claimed families from patients B-CLL cells, and vectors, cells, the antibodies, methods of determining the gene families.

Fais et al teach VH genes and VH amino acid sequences from B-CLL cells and the genes are from the members claimed (see Tables). Fais et al does not teach the VL genes or antibody amino acid sequences. This deficiency is made up for in the teachings of Damle et al and Valetto et al.

Damle et al teach that the VL genes from B-CLL cells have only 10% mutations and can be in two categories (see page 1840). Valetto et al teach the VL genes in B-CLL cells are greater than 97% similar and are in the VK 012 and JK1 families (see abstract).

It would have been obvious to obtain both the VH and VL genes and to determine the families of the genes in view of the references. One would have been motivated to do so because Fais et al teach categorizing the VH genes and both Damle and Valetto et al discuss the VH and VL genes and Valetto et al teach that the VL are from a specific family that is claimed.

Therefore, claims 1-23, 78-92, 103, 110, 116 lacks an inventive step under PCT Article 33(3) as being obvious over Fais et al in view of Damle et al and Valetto et al.